UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,303	06/02/2005	Martin Meise	2923-703	2146

6449 7590 10/22/2007

ROTHWELL, FIGG, ERNST & MANBECK, P.C.
1425 K STREET, N.W.
SUITE 800
WASHINGTON, DC 20005

EXAMINER	
SAIDHA, TEKCHAND	
ART UNIT	PAPER NUMBER
1652	

NOTIFICATION DATE	DELIVERY MODE
10/22/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

Office Action Summary	Application No.	Applicant(s)	
	10/537,303	MEISE ET AL.	
	Examiner	Art Unit	
	Tekchand Saidha	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 September 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29 and 33-39* is/are pending in the application.

4a) Of the above claim(s) *1-15,18-29 and 33-37* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16,17,28,29,38 and 39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 June 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-29 & 33-39 are present in this application.

2. ***Election***

Applicant's election of Group II (claims 16-17, 28-29 and new claims 38-39), filed 9/13/07, drawn to a method of treatment for of obesity, diabetes and/or metabolic syndrome using the *PRL1* DNA sequence of SEQ ID NO: 1, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

3. **Claims withdrawn**:

Claims 1-15, 18-29, 33-37 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

4. ***Priority***

Acknowledgment is made of applicants' claim for foreign priority based on an application filed in EPO on 12.03.2002.

5. ***Drawings***

Drawings filed on 6.2.2005 are acknowledged.

6. ***Specification***

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

7 ***Claim Objections***

Claims 16-17 & 28-29 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in

independent form. The claims either directly or indirectly depend from non-elected claims or recite non-elected subject matter. Applicants are required to correct the dependency and include the required elected subject matter.

Subject matter elected include the DNA of SEQ ID NO: 1. Polypeptides and/or modulators of polypeptide/DNA is non-elected subject matter. Applicants are required to cancel the non-elected subject matter.

8. Claims 16-17 & 28-29 provides for the use of *PRL1* DNA sequence [SEQ ID NO: 1], but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 16-17 & 28-29 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd. App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

9. ***Claim Rejections - 35 USC § 112*** (second paragraph)

Claims 16-17 & 28-29 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 16-17 & 28-29 recite the 'use of the elected DNA of SEQ ID NO: 1 as well as the 'manufacture of the DNA for medicament for treating obesity, diabetes, etc.

The claims are confusing because it is not clear what process is being claimed. Perhaps Applicants intend to claim 'a method of treatment', as per the election and inclusion of new claims 38-39. Correction is required to suitably amend the claims to a single method with defined steps.

10. ***Written Description***

For the purpose of this rejection (WD), the claims are being rejected as being drafted for 'a method of treating obesity, etc., in a patient using effective amount of human *PRL-1* nucleic acid'.

Claims 16-17, 28-29 and 38-39 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims are directed to a method of treating obesity, etc., in a patient using a genus of therapeutically effective amount of human *PRL-1* nucleic acid or that encoding *PRL-1* homologous protein, or isoforms, functional fragment or variant thereof with no defined function.

The specification does not contain any disclosure or description of the structure and function of all DNA sequences that are variants of human *PRL-1* nucleic acid having the desired activity or function with no description of therapeutically effective amount of human *PRL-1* nucleic acid required for the method of treating obesity, diabetes, metabolic syndrome, eating disorder, cachexia, coronary heart disease, hypercholesterolemia, dyslipidemia, osteoarthritis, gallstone, or liver fibrosis.

The instant specification describe selected species by way of *in vitro* assays for the determination of triglyceride and glycogen levels in cell over-expressing Prl-1 (Figure 5). Figure 6A shows a decrease in lipid synthesis level in Prl-1 LOF cells. However, the specification lack description of the effects of administered human *PRL-1* nucleic acid (or the modulators of the DNA) on LOF cells or in specific mouse models, and with respect to any of the diseases claimed.

The specification discloses the PRL-1 DNA sequence of SEQ ID No. 1 as well as DNA sequences of PRL-2 and PRL-3 of the claimed genus which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. These species sequences are not representative of the entire protein tyrosine phosphatases DNA used or shown to be effective in the method claimed. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

11. ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraph of 35 U.S.C. § 102 in view of the AIPA and H.R. 2215 that forms the basis for the rejections under this section made in the attached Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the

treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 16-17, 28-29 and 38-39 are rejected under 35 U.S.C. 102(e) as being anticipated by Accession no. ADN03661. [*See* the enclosed sequence search alignment between Accession no. ADN03661 and Applicants' SEQ ID NO: 1]

Accession No. ADN03661 is described in [Bodary et al., WO2004028479-A2, priority 25 September 2002]. Bodary et al. teach a DNA sequence of Accession no. ADN03661, which is 100% identical to Applicants' SEQ ID NO: 1 and used in a gene therapy for treatment of psoriasis. The instant method of treating diseases and disorder include metabolic syndrome and related disorder with no express definition to the extent of these diseases and disorder or which are explicitly limited to; and the polynucleotide or the PRL1 DNA variants used in the method; is comprised by the teachings of the Boadary.

12. ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 16-17, 28-29 & 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Au-Young et al. [WO 99/14340, *cited in the* **IDS**]. Au-Young et al. teach DNA encoding human PRL-1 and methods using the DNA and protein for treating inflammation,

cancer, arteriosclerosis and psoriasis. *See* abstract, page 1, 15 and the entire document.

13. No claim is allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tekchand Saidha whose telephone number is (571) 272 0940. The examiner can normally be reached on 8.30 am - 5.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (571) 272 0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Tekchand Saidha
Primary Examiner, Art Unit 1652
Recombinant Enzymes, 02A65 Remsen Bld.
400 Dulany Street, Alexandria, VA 22314
Telephone: (571) 272-0940
October 15, 2007